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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/974,584 | 11/19/1997 | THOMAS R. CECH | 015389-00295 | 8401 |

34151 7590 04/09/2004

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EXAMINER

MYERS, CARLA J

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1634

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/974,584

Applicant(s)

CECH ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004 and 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 119-127 is/are pending in the application.
- 4a) Of the above claim(s) 127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 119-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to the amendment filed January 30, 2004. Applicants arguments and amendments set forth in the response of January 30, 2004 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Election/Restrictions

2. Applicant's election of Group 11, polynucleotides encoding telomerase reverse transcriptase, corresponding to present claims 119-126, in the response of January 9, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the response of January 30, 2004, Applicants state that claim 119 should be rejoined with the claims currently under consideration upon the allowance of the product claims. However, the present claims are not allowable for the reasons set forth below.

Information Disclosure Statement

3. In the information disclosure statement filed February 17, 2004, the references listing U.S. Application No's have been crossed off because copending U.S. applications are not appropriately listed in information disclosure statements. However, these copending applications have been considered by the Examiner.

Oath/Declaration

4. The Oath/Declaration is not consistent with the information provided in the first line of the specification. The Oath/Declaration indicates that foreign priority is claimed to

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PCT/US97/17168 and PCT/US97/17885. However, the first line of the specification indicates that the present application is a CIP of each of these PCT applications. The first line of the specification should be amended so that the information set forth therein is consistent with the Oath/Declaration or a new Oath/Declaration should be filed which indicates that the present application is a CIP of PCT/US97/17168 and PCT/US97/17885.

In the response of January 30, 2004, Applicants state that they will "obtain a new executed Declaration from the inventors as requested, or otherwise address this issue." Accordingly, the rejection is maintained for the reasons stated above.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 123-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide basis for the concepts set forth in newly added claims 123-126 of: defining structure c) as limited to SEQ ID NO: 478 (claim 123); defining structure e) as limited to SEQ ID NO: 370 (claim 124); defining structure e) as limited to SEQ ID NO: 479 (claim 125); or for a polynucleotide that

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encodes a telomerase containing any 10 amino acids of SEQ ID NO: 123 in place of or in addition to the amino acids set forth in claim 119 (claim 126). The specification as originally filed discloses the concept of "isolated naturally occurring and recombinant TRT proteins comprising one or more of the motifs illustrated in Figures 55 and 57." The specification provides an example of the motifs that may be included in said telomerase. However, the specification does not specifically teach that structure b) may be SEQ ID NO: 478, structure d) may be SEQ ID NO: 370 and structure e) may be SEQ ID NO: 479. Furthermore, with respect to claim 126, the specification exemplifies a partial cDNA TRT clone encoding a protein having the amino acid sequence of SEQ ID NO: 123. However, the specification does not provide support for the claimed genus of a polynucleotide encoding any TRT comprising any 10 mer amino acid fragment of SEQ ID NO: 118 present in addition to any one of structures a-f as defined in claim 119.

RESPONSE TO ARGUMENTS:

In the response of January 30, 2004, Applicants state that Figure 55 provides support for claims 123-125 and that the specification at pages 16 and 46 provide support for the concept of TRT fragments of 10 consecutive amino acids.

Applicants statements have been fully considered but are not persuasive to overcome the present grounds of rejection. While a drawing may be used to provide support for a claimed invention, the drawing must describe the complete invention that is being claimed. In the present case, Figure 55 lists a number of sequence motifs. However, this figure does not describe specific TRT nucleic acids defined in terms of

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comprising the sequences set forth in claim 119 wherein the sequences are further defined such that structure b) may be SEQ ID NO: 478, structure d) may be SEQ ID NO: 370 and structure e) may be SEQ ID NO: 479. The teaching of particular motifs consisting of SEQ ID NO: 478, 370 and 479 does not provide basis for the claimed genus of nucleic acids. Further, while page 46 of the specification refers to peptide immunogens that may be of a length of about 10 amino acids and page 16 refers to antibodies that bind to a portion of a TRT peptide, the specification does not provide basis for the claimed genus of a polynucleotides encoding any TRT comprising any 10 mer amino acid fragment of SEQ ID NO: 118 present in addition to any one of structures a-f as defined in claim 119.

6. Claims 119-126 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides encoding telomerase reverse transcriptase wherein the polynucleotides comprise SEQ ID NO: 1, 51, 53, 666, 68, 417 or 419, does not reasonably provide enablement for any polynucleotide encoding a protein having telomerase reverse transcriptase activity wherein the polynucleotide comprises the motifs set forth in claim 119. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following factors have been considered in formulating this rejection (*In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988): the breadth of the claims, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance

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presented, the presence or absence of working examples of the invention and the quantity of experimentation necessary.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art Furthermore, the Court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(l)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". In the instant case, the specification has not provided sufficient guidance to enable the skilled artisan to make and use the invention as it is broadly written for the following reasons:

Firstly, it is noted that the claims are drawn broadly to encompass a very large genus of polynucleotides. In particular, the claims are drawn to polynucleotides encoding a telomerase having telomerase catalytic activity wherein the polypeptide has each of the structures of e) SEQ ID NO: 16 or 17, a) SEQ ID NO: 139, b) SEQ ID NO: 143, c) SEQ ID NO: 144, d) SEQ ID NO: 146, and e) SEQ ID NO: 147. The stated sequences represent conserved motifs shared by telomerase reverse transcriptase (TRT). Each of these sequences include variable amino acid positions which may be

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any amino acid (X) or may be Leu or Ile (R1), Gln or Arg (R2), Phe or Tyr (R3) or Lys or His (R4), as set forth in claim 119 and in the sequence listing. The amino acids present between these motifs, the exact amino acid sequence of these motifs, the order of the motifs, the length of the amino acid sequence, and the source of the amino acid sequence are not set forth in the claims. The claims include genomic DNA sequences, splice variants, insertion, deletion and substitution variants having an increased or decreased level of telomerase reverse transcriptase activity, and polynucleotides encoding TRTs from any species.

The specification teaches a limited number of polynucleotides encoding telomerase reverse transcriptase proteins. Specifically, the specification teaches isolated cDNAs encoding telomerase proteins from *Euplotes aediculatus*, *Oxytricha*, *Saccharomyces cerevisiae*, *Tetrahymena*, *Schizosaccharomyces pombe*, mouse and human. The specification also teaches the genomic DNA encoding *E. aediculatus* telomerase (SEQ ID NO: 1). Further, the specification also teaches a single variant of human telomerase wherein the cDNA (SEQ ID NO: 117) encoding this polypeptide has a 182 bp deletion (see, for example, page 38 of the specification). The specification provides an alignment of TRT proteins and identifies particular regions within these protein sequences that are conserved amongst TRT proteins. The specification also teaches the general methodology for using known TRT nucleic acids to identify additional TRT nucleic acids.

However, the scope of the claims does not bear a reasonable correlation to the scope of enablement provided by the specification. The teachings in the specification of

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7 specific polynucleotides does not enable one of skill in the art to obtain a representative number of polynucleotides within the broadly claimed genus without undue experimentation. The claims are inclusive of polynucleotides which are defined only in terms of the fact that they contain 6 consensus motifs. The claims do not define the overall structure of the protein encoded by the polynucleotide. The claims include splice variant and mutant polynucleotides that contain nucleotide additions, deletions and substitutions. The claims further include variants that have increased or decreased levels or altered telomerase activity as compared to wild-type sequences. However, the specification teaches only one variant human TRT which contains a 182 bp deletion. It is noted that this particular variant appears to be excluded from the claims because the claims require a polynucleotide encoding motif B' (SEQ ID NO: 146) and motif C (SEQ ID NO: 147) and these motifs are not present in the variant having a 182 bp deletion. The specification highlights the unpredictability in determining the effect of nucleotide alterations on the function of the encoded protein. In particular, the specification at page 38 states that "(a)lthough the hTRT variants lacking the 182 basepair sequence found in the pGRN121 cDNA (SEQ ID NO: 117) are unlikely to encode a fully active telomerase catalytic enzyme, they may play a role in telomerase regulation and/or have partial telomerase activity, such as telomere binding or hTR binding activity." The specification has not identified any particular nucleotides within the TRT gene or cDNA which may be altered without effecting the functional activity of the encoded protein. Furthermore, the specification does not provide sufficient guidance to enable the skilled artisan to determine which alterations in any TRT gene can be made without altering the

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functional properties of the encoded protein. In view of the breadth of the claims and the unpredictability in the art and lack of specific guidance provided in the specification, undue experimentation would be required to practice the invention as it is broadly claimed.

RESPONSE TO ARGUMENTS:

In the response filed January 30, 2004, Applicants traversed this rejection by arguing that the specification provides guidance as to how to make alterations in the claimed nucleic acids. Applicants note that the claims have been amended to recite that the nucleic acid has 60% identity with SEQ ID NO: 118. Applicants also argue that methods for making mutations are known in the art and methods for detecting the functionality of nucleic acids are described in the specification. It is asserted that making and screening for TRT variants is routine and thereby the specification is enabling for the full scope of the claimed invention.

Applicants arguments have been fully considered but are not persuasive to overcome the present grounds of rejection. It is agreed that general methods of mutagenesis and methods of assaying for telomerase activity were known in the art at the time the invention was made. However, teaching how to search for molecules having telomerase activity is not equivalent to teaching specific nucleic acid sequences having telomerase catalytic activity. While the specification defines domains conserved between telomerase proteins, it remains unpredictable as to what degree of modification within these domains may be tolerated without altering the overall 3-dimensional structure and functional activity of the protein and what modifications outside of these

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domains will not alter the functional activity of the protein. Following Applicants method as proposed in the amendment, one would use random mutagenesis to generate 20¹¹³² potential variants of SEQ ID NO: 118, remove the members from this genus that do not contain the motifs specified in claim 119, and then assay this very large genus of variants to determine which of the variants has telomerase catalytic activity. In view of the unpredictability in the overall structure-function relationship, such random experimentation is considered to be undue. Again, the teachings in the specification of 1 variant, which variant is actually excluded from the claims, does not provide adequate teachings and guidance to enable the skilled artisan to make and use the claimed genus of mutants, allelic variants, splice variants, and homologues.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 119-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 120 is indefinite because it is not clear as to whether the protein includes SEQ ID NO: 116 in addition to the structures a-f or if SEQ ID NO: 116 represents one of the structures of a-f. It is noted that pages 43-44 of the specification describe a TRT which contains either Motif T (which may be defined as SEQ ID NO: 16 or 17) or SEQ ID NO: 116.

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Claim 121 is indefinite because it is not clear as to whether SEQ ID NO: 477 may be attached at either terminus of SEQ ID NO: 16 or 17 and whether additional amino acids may be inserted between SEQ ID NO: 16/17 and SEQ ID NO: 477.

Claim 122 is indefinite because it is unclear as to the relationship between SEQ ID NO: 473 and structure a). It is unclear as to whether structure b is SEQ ID NO: 473 or if SEQ ID NO: 473 is attached to either terminus of SEQ ID NO: 139 and/or if additional unspecified amino acids may be inserted between SEQ ID NO: 139 and SEQ ID NO: 473. Similarly, claims 123-125 are indefinite because it is not clear as to what is intended to be the relationship between SEQ ID NO: 478 and structure b), SEQ ID NO: 370 and structure d) and SEQ ID NO: 479 and structure d).

RESPONSE TO ARGUMENTS:

In the response filed January 30, 2004, Applicants traversed the above rejections by stating that each of the alternatives is permitted by the claims, and thereby no indefiniteness exists. However, it is not clear as to which embodiments are encompassed by the claims as written. With respect to the rejection over claim 120, the "reader" would not in fact understand that the structure set forth in the claim is an elaboration of a motif from claim 119 since the claim fails to include such a recitation. With respect to claims 121-125, one would not understand from Figure 55 that the claims were intended to include concatenated sequences. Limitations from the specification are not read into the claims. Further, Applicants interpretation that the claims may include concatenated sequences emphasizes the indefiniteness and lack of clarity of the claims since it would not be readily apparent that the stated sequences

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could be concatenated to the terminus of the motifs set forth in claim 119 and still maintain the requirement for 60% identity to SEQ ID NO: 118 (as is now recited in the amended claims).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

. Claims 119-126 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,093,809.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are drawn generically to encompass polynucleotides encoding a telomerase reverse transcriptase (TRT) protein and the claims of '809 are drawn to a polynucleotide encoding a specific telomerase protein such that the genus of polynucleotides set forth in the present claims encompasses the species set forth in the claims of '809. In particular, the present claims are drawn to a polynucleotide encoding a TRT protein wherein the protein contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. The claims of '809 are drawn to

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polynucleotides encoding a telomerase protein wherein the polynucleotide hybridizes under stringent conditions to SEQ ID NO: 1 and to variants and fragments thereof. The polynucleotides of SEQ ID NO: 1 encode for a protein having the motifs of present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides claimed in '809 are encompassed by the presently claimed polynucleotides encoding any TRT.

RESPONSE TO ARGUMENTS:

In the response filed January 30, 2004, Applicants state that they will file a terminal disclaimer or take other appropriate action upon the indication of allowance of the claims. The rejection is maintained and made final for the reasons stated above.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,093,809).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding *Euplotes aediculatus*, *Schizosaccharomyces*, *Saccharomyces* and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

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11. Claims 119-126 are rejected under 35 U.S.C. 102(e) as being anticipated by Cech (U.S. Patent No. 6,309,867).

It is noted that the claims are entitled to the present filing date of 11/19/1997. It is further noted that a claim as a whole is assigned an effective filing date (rather than the subject matter within a claim being assigned individual effective filing dates). The applications to which priority is claimed do not provide basis for the presently claimed subject matter of a genus of polynucleotides encoding a protein having telomerase catalytic activity wherein the proteins comprise each of the structures of the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Additionally, it is pointed out that the inventorship of the '809 patent is distinct from that of the present application. Additionally, while the record indicates that the present application was assigned to the University of Technology Corporation and Geron Corporation as of 07/17/1997, there is no evidence on the record to establish common ownership at the time the invention was made.

Cech et al teach isolated polynucleotides encoding telomerase reverse transcriptase proteins (TRT) and specifically teaches polynucleotides encoding *Euplotes aediculatus*, *Schizosaccharomyces*, *Saccharomyces* and human telomerase. Each of these TRT proteins contains the motifs set forth in SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147. Accordingly, the polynucleotides disclosed by Cech anticipate the claimed invention.

12. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Linger et al (Gen Bank Accession No.U95964).

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Linger teaches an isolated polynucleotide encoding the p123 telomerase subunit of *Euplotes aediculatus*. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

13. Claim 119 is rejected under 35 U.S.C. 102(a) as being anticipated by Lendvay (Genetics (Dec 1996) 144: 1399-1412: cited in the IDS).

Lendvay teaches an isolated polynucleotide EST2 gene encoding the telomerase subunit of *Saccharomyces cerevisiae*. The protein encoded by the polynucleotide of Linger contains the motifs set forth in present SEQ ID NO: 16 or 17, 139, 143, 144, 146, and 147.

RESPONSE TO ARGUMENTS:

In the response filed January 30, 2004, Applicants traversed each of the above 102 rejections by stating that the cited art is not prior art to the claimed invention. Applicants state that the present application claims priority to 08/724,643, filed October 1, 1996 and that each of the cited references has a later publication or filing date. However, a statement of priority to an early application does not necessarily entitle one to this priority. The '643 application does not provide basis for each of the limitations set forth in claims 119-126. Applicants have not pointed to any particular teachings in the '643 application which provide specific basis for the genus of polynucleotides set forth in the present claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
April 7, 2004


CARLA J. MYERS
PRIMARY EXAMINER